

PREVAILED

Roll Call No. _____

FAILED

Ayes _____

WITHDRAWN

Noes _____

RULED OUT OF ORDER

HOUSE MOTION _____

MR. SPEAKER:

I move that Engrossed Senate Bill 10 be amended to read as follows:

- 1 Page 1, line 3, delete "(a)".
- 2 Page 1, line 5, delete ":".
- 3 Page 1, line 6, delete "(1)".
- 4 Page 1, line 7, delete "; and" and insert ".".
- 5 Page 1, run in lines 5 through 7
- 6 Page 1, delete lines 8 through 12.
- 7 Page 1, between lines 12 and 13, begin a new paragraph and insert:
- 8 "SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS
- 9 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 35. (a) As used in this
- 10 section, "single source drug" means a covered outpatient drug that is
- 11 produced or distributed under an original new drug application
- 12 approved by the federal Food and Drug Administration, including a
- 13 drug product marketed by any cross-licensed producers or distributors
- 14 operating under the new drug application.
- 15 (b) Before the ~~approval or implementation~~ of a **board places a**
- 16 **single source drug on** prior approval, ~~program for outpatient single~~
- 17 ~~source drugs, restricts the drug in its use, or establishes~~ a drug
- 18 monitoring process or program to measure or restrict utilization of
- 19 single source drugs other than in the SURS program, the ~~program~~
- 20 **board** must meet the following conditions:
- 21 (1) ~~An outpatient single source drug may not be placed on prior~~
- 22 ~~approval or restricted in its use for other than medical reasons.~~
- 23 **Make a determination after considering evidence and**
- 24 **information provided to the board by the office and the public**

1 that placing a single source drug on prior approval or
 2 restricting the drug's use will not impede the quality of
 3 patient care.

4 (2) ~~Before a single source drug is placed on prior approval or~~
 5 ~~restricted in its use; the board must~~ Hold a public hearing under
 6 IC 4-22 at least ninety (90) days before taking the action.

7 (3) ~~The board must~~ Provide evidence that placing a single source
 8 drug on prior approval or restricting its use will not: ~~impede the~~
 9 ~~quality of patient care and that the single source drug is subject to~~
 10 ~~clinical abuse or misuse before the board recommends that the~~
 11 ~~drug be placed on prior approval or restricted in its use.~~

12 (A) **increase costs in other parts of the Medicaid program,**
 13 **including hospital costs and physician costs; and**

14 **(B) result in less than optimal therapeutic outcomes.**

15 (4) ~~Any single source drug placed on prior approval or restricted~~
 16 ~~in its use will be reconsidered for~~ **Reconsider the** removal from
 17 its restricted status by the board from prior approval not later than
 18 six (6) months after the single source drug is placed on prior
 19 approval or restricted in its use.

20 (5) ~~Any prior approval program~~ **Must provide ensure that the**
 21 **program provides** either telephone or FAX approval or denial
 22 Monday through Friday, twenty-four (24) hours a day. The office
 23 must provide the approval or denial within twenty-four (24) hours
 24 after receipt of a prior approval request. The program must
 25 provide for the dispensing of at least a seventy-two (72) hour
 26 supply of the drug in an emergency situation or on weekends.

27 (6) **Ensure that** any prior approval program or restriction on the
 28 use of a single source drug ~~may is not be~~ applied to prevent
 29 acceptable medical use for appropriate off-label indications.

30 (c) The DUR board shall advise the office on the implementation of
 31 any program to restrict the use of brand name multisource drugs.

32 **(d) This section does not prohibit the board from considering**
 33 **health, economic, or cost data."**

34 Renumber all SECTIONS consecutively.

(Reference is to ESB 10 as printed March 30, 1999.)

Representative Welch